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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,986	07/24/2003	Li-Huei Tsai	10498-00054	3395

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EXAMINER	
BALLARD, KIMBERLY A	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,986	TSAI ET AL.	
	Examiner	Art Unit	
	Kimberly A. Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-100* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, 33-44, and 46-56, drawn to a method of treating an individual afflicted with Alzheimer's disease comprising administering a compound which inhibits amyloid precursor protein phosphorylation, classified for example in class 514, subclass 1.

II. Claims 23-32, drawn to a method of diagnosing Alzheimer's disease in a patient, classified for example in class 435, subclass 4.

III. Claim 45, drawn to a compound for inhibiting cleavage of amyloid precursor protein (APP), wherein the compound inhibits phosphorylation of an amino acid residue of APP, classified for example in class 514, subclass 1.

IV. Claims 57-72, drawn to a method of identifying a compound that inhibits symptoms associated with Alzheimer's disease, classified for example in class 435, subclass 7.1.

V. Claims 73-84, drawn to a transgenic mouse, classified for example in class 800, subclass 18.

VI. Claim 85, drawn to a cell line established from a transgenic mouse, classified for example in class 435, subclass 354.

VII. Claims 86-93, drawn to an assay for determining the effect of a compound on a feature of a neurodegenerative disorder comprising testing said

compound on transgenic mice, classified for example in class 800, subclass 3.

VIII. Claims 94-100, drawn to an assay for determining the effect of a compound on a feature of a neurodegenerative disorder comprising testing said compound on a transgenic cell line, classified for example in class 435, subclass 354.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-II, IV, and VII-VIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions I-II, IV, and VII-VIII are directed to methods that are distinct from each other in reagents, steps, and outcomes or functions, and are not required one for the other. For example, the method of Invention I treats Alzheimer's disease, which would require search and examination of a specific patient population, whereas the methods of Invention II diagnose Alzheimer's disease in patients and Invention IV screens compounds for use in treatment of Alzheimer's disease therapy. The methods of Inventions VII-VIII determine the effects of compounds on a feature of neurodegenerative disease, neither of which are required or recited by Inventions I, II or IV. Invention VII administers compounds *in vivo* to transgenic mice, whereas Invention

VIII exposes transgenic cell lines to the compounds *in vitro*, with each Invention having distinct outcomes and assessment steps.

Inventions III, V, and VI are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions III, V, and VI are directed to products that are distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention and which cannot be exchanged. The compound of Invention III is not required or recited by the transgenic mouse of Invention V or the cell line of Invention VI. Furthermore, the cell line of Invention VI could be made independently of the transgenic mouse of Invention V by stably transfecting the cells.

Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Invention III could be used for *in vitro* testing instead of being administered *in vivo* to individuals afflicted with Alzheimer's disease.

Inventions III and each of II, IV, VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Invention III and each of II, IV, VII and VIII are unrelated product and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions II, IV, VII and VIII do not recite the use or production of the compound of Invention II.

Inventions (V-VI) and each of I, II, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Invention (V-VI) and each of I, II and IV are unrelated product and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions I, II and IV do not recite the use or production of the transgenic mouse of Invention V or the cell line of Invention VI.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic mouse of Invention V could be used to produce a protein specifically related to Alzheimer's disease therapy. Also, the method of Invention VII could be practiced with

a different transgenic mouse model for a different neurodegenerative disease, such as Parkinson's disease.

Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Invention V and VIII are unrelated product and process, wherein each is not required, one for another. For example, the claimed methods of Inventions VIII do not recite the use or production of the transgenic mouse of Invention V.

Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Invention VIII could be practiced with non-transgenic cells or transgenic cells other than those of Invention VI.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Invention VI and VII are unrelated product and process, wherein each is not required, one for another. For example, the claimed

methods of Inventions VII do not recite the use or production of the cell line of Invention VI.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for any other group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

The Examiner notes that the method claims 46-56 are improperly dependent upon the product claim 45. Applicant is advised to make appropriate corrections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kimberly Ballard, PhD
Art Unit 1649
December 5, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER